Section 10

JUN - 2 2000

K001427

510(k) SUMMARY
(Summary of Safety and Effectiveness)

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Carol A. Adiletto, M.S.
Director of Clinical Affairs
Selfcare, Inc.
200 Prospect Street
Waltham, MA 02453-3457 USA

Phone: (781) 647-3900 x124
Fax: (781) 647-3939
Email: carol.adiletto@usa.invernessmedical.com

This summary was prepared on May 04, 2000.

2. Name of the device:

Fast*Take*® Blood Glucose Monitoring System, is intended for home use. Classification name(s) are as follows:

Classification	ProCode	Description
862.1345 Class II	75 CGA	Glucose Monitor
862.1660 Class I	75 JJX	Single analyte control
878.4800 Class I	79 FMK	Lancet, blood

3. Substantial Equivalence

The new device is substantially equivalent to the previously cleared FastTake® Compact Blood Glucose Monitoring System, marketed pursuant to K000583.

4. Description of changes

The modification provides the user with the arm as an additional site to collect capillary blood for self monitoring of glucose, and is thus an ergonomic option for the user's accommodation. This provides the user with an alternate site to fingersticks. An additional control solution has been qualified for use with the Fast*Take*® system and will be marketed as one of the components.

5. Intended use(s):

The new device has the same intended use as the legally marketed predicate device. It is used for the quantitative measurement of glucose in fresh capillary whole blood. The Fast*Take*® Compact Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.

6. Statement of How the Technological Characteristics of the Device Compare to the Predicate device:

The new device has the same technological characteristics as the legally marketed predicate device.

7. Summary of Performance Data:

As there are no changes to the meter, strip, or to the software requirement specifications, minimal verification testing was requisite to confirm that the FastTake functions and operates with substantial equivalence to the predicate. A hazard analysis was conducted to identify and evaluate the risks that may be associated with this user interface change and address the mitigation goals and control activities. Clinical performance evaluations were also done to address this change with the perspective of the device users. Clinical performance evaluations using the Fast*Take*® Compact Blood Glucose Monitoring System components were conducted to validate the professional accuracy, consumer accuracy and consumer use. Test results showed substantial equivalence. No adverse events occurred during the studies. The results demonstrate that the FastTake® Compact Blood Glucose Monitoring System meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol A. Adiletto, M.S.
Director of Clinical Affairs
Selfcare, Inc.
200 Prospect Street
Waltham, Massachusetts 02453

JUN - 2 2000

Re: K001427
Trade Name: Lifescan FastTake® Blood Glucose Monitoring System
Regulatory Class: II
Product Code: CGA
Regulatory Class: I
Product Code: JJX
Dated: May 5, 2000
Received: May 5, 2000

Dear Ms. Adiletto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 Labeling and "Indications for Use" Statement

4.1 ODE INDICATIONS STATEMENT

Indications for Use Statement

510(k) Number: K001427

Device Name: Lifescan Fast*Take*® Blood Glucose Monitoring System

Indications for Use:

The Fast*Take*® Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The Fast*Take*® System is intended for use outside the body (*in vitro* diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.

Jean Cooper

(Division Sign
Division of Cli
510(k) Number K001427

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ~~X~~ OR Over-The-Counter Use X
(Per 21 CFR 801.109)